

That which is claimed is:

1. In a human subject in need of treatment with a therapeutic compound for an EGFR-expressing or erbB2-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor compound, comprising:
  - (a) determining the pre-treatment relative localization of pERK in cells of said tumor;
  - (b) administering a therapeutically effective amount of a dual EGFR/erbB2 tyrosine kinase inhibitor; and
  - (c) determining the relative localization of pERK in cells of said tumor after an initial period of treatment with said therapeutic agent,where a shift in relative pERK localization from the nucleus to the cytoplasm indicates said subject is more likely to exhibit a favorable clinical response to treatment with said therapeutic agent, compared to a subject with no change in relative pERK localization.
2. A method according to claim 1 where said initial period of treatment is the time required to achieve a steady-state plasma concentration of said therapeutic compound.
3. A method according to claim 1 where p-erk levels are assessed by immunohistochemical methods.
4. A method according to claim 1 where said tumor over-expresses EGFR or erbB2.
5. A method according to claim 1 where said solid tumor is an epithelial tumor.
6. A method according to claim 1 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.
7. A method according to claim 1 where said therapeutic agent is GW572016.

8. A method according to claim 1 where said therapeutic agent is GW572016 and said initial treatment period is from about 14 days to about 28 days.
9. A method according to claim 1, further comprising determining the relative localization of pAKT in cells of said tumor pre-treatment and after the initial period of treatment.
10. In a human subject in need of treatment with a therapeutic compound for an EGFR-expressing or erbB2-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor compound, comprising:
  - (a) determining the pre-treatment relative localization of pAKT in cells of said tumor;
  - (b) administering a therapeutically effective amount of a dual EGFR/erbB2 tyrosine kinase inhibitor; and
  - (c) determining the relative localization of pAKT in cells of said tumor after an initial period of treatment with said therapeutic agent,where a shift in relative pAKT localization from the nucleus to the cytoplasm indicates said subject is more likely to exhibit a favorable clinical response to treatment with said therapeutic agent, compared to a subject with no change in relative pAKT localization.
11. A method according to claim 10 where said initial period of treatment is the time required to achieve a steady-state plasma concentration of said therapeutic compound.
12. A method according to claim 10 where p-AKT levels are assessed by immunohistochemical methods.
13. A method according to claim 10 where said tumor over-expresses EGFR or erbB2.
14. A method according to claim 10 where said solid tumor is an epithelial tumor.

15. A method according to claim 10 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.
16. A method according to claim 10 where said therapeutic agent is GW572016.
17. A method according to claim 10 where said therapeutic agent is GW572016 and said initial treatment period is from about 14 days to about 28 days.
18. A method according to claim 10 further comprising determining the relative localization of pErk in cells of said tumor pre-treatment and after the initial period of treatment.
19. In a human subject in need of treatment with a therapeutic compound for an EGFR-expressing or erbB2-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor compound, comprising determining the pre-treatment relative localization of pERK in cells of said tumor; where increased localization of pERK in the nucleus of tumor cells compared to localization in the cytoplasm indicates that the subject is not as likely to exhibit a favorable clinical response to said treatment, compared to a subject without increased nuclear localization of pERK.
20. A method according to claim 19 where p-erk levels are assessed by immunohistochemical methods.
21. A method according to claim 19 where said tumor over-expresses EGFR or erbB2.
22. A method according to claim 19 where said solid tumor is an epithelial tumor.
23. A method according to claim 19 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.

24. A method according to claim 19 where said therapeutic agent is GW572016.
25. A method according to claim 19, further comprising determining the relative localization of pAKT in cells of said tumor.
26. In a human subject in need of treatment with a therapeutic compound for an EGFR-expressing or erbB2-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor compound, comprising determining the pre-treatment relative localization of pAKT in cells of said tumor; where increased localization of pAKT in the nucleus of tumor cells compared to localization in the cytoplasm indicates that the subject is not as likely to exhibit a favorable clinical response to said treatment, compared to a subject without increased nuclear localization of pAKT.
27. A method according to claim 26 where p-AKT levels are assessed by immunohistochemical methods.
28. A method according to claim 26 where said tumor over-expresses EGFR or erbB2.
29. A method according to claim 26 where said solid tumor is an epithelial tumor.
30. A method according to claim 26 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.
31. A method according to claim 26 where said therapeutic agent is GW572016.
32. A method according to claim 26, further comprising determining the relative localization of pErk in cells of said tumor.

33. In a human subject in need of treatment with a therapeutic compound for an EGFR-expressing or erbB2-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor compound, comprising determining the pre-treatment level of ErbB2 in cells of said tumor; where increased amounts of ErbB2 in tumor cells indicates that the subject is more likely to exhibit a favorable clinical response to said treatment, compared to a subject with lesser amounts of ErbB2 in the tumor cells.

34. A method according to claim 33 where p-ErbB2 levels are assessed by immunohistochemical methods.

35. A method according to claim 33 where said tumor over-expresses EGFR or erbB2.

36. A method according to claim 33 where said solid tumor is an epithelial tumor.

37. A method according to claim 33 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.

38. A method according to claim 33 where said therapeutic agent is GW572016.

\* \* \*